DETAILED ACTION

Claims 57-61 are pending and are considered on the merits.

Claim Rejections - 35 USC § 103

Claims 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney *et al.* [AW] in combination with US 5,747,536 [AA] and Ogawa *et al.*[U] and Tegos *et al.*[V].

The claims are directed to a method comprising:
adding L-carnitine or an ester of carnitine to a platelet concentrate which has been leukodepleted and suspending the platelet concentrate in the mixture.

The intent of the claimed methods is the suppression of bacterial growth in the platelet concentrate.

Sweeney *et al.* disclose a method of adding L-carnitine or acetyl-carnitine (5mM) to platelet concentrates and agitating the mixture. This is said to reduce glycolysis in the platelet mixture.

Tegos *et al.* teach that glycolytic enzymes are present in isolated platelets.

Ogawa *et al.* teach the advantages of leukodepleting platelet products with regard to prevention of adverse reactions to PC transfusion.

US 5,747,536 discloses that esters of carnitine other than acetyl ester are known.

The primary reference lacks the disclosure of leukodepleting the platelet concentrate and use of the homologous derivatives of acetyl-carnitine.

The substitution of other esters of carnitine such as butyryl, valeryl, propionyl, isobutyryl for the acetyl ester of carnitine in the method of Sweeney

et al. would have been obvious when US 5,747,536 was taken with Sweeney *et al.* because US 5,747,536 lists various esters of carnitine and also further discloses the addition of carnitine or its derivatives to platelet concentrates. In the absence of evidence to the contrary, the salts and esters of L-carnitine would reasonably be expected to have a similar activity to L-carnitine or acetylcarnitine because these are simple homologs which may be reasonably expected to have similar properties and activities in the absence of evidence to the contrary.

The substitution of a leukodepleted platelet concentrate for the platelet concentrate of the primary reference would have been obvious because both a nonleukodepleted platelet concentrate and a leukodepleted platelet concentrate comprise platelets, and platelets possess the glycolytic enzymes, see Tegos *et al.* which result in glycolysis during storage. Therefore, even if the leukocytes are removed for advantages known in the art, see Ogawa *et al.*, glycolysis in the preparation would still be expected to occur. Thus, the addition of L-carnitine, salts or esters thereof, to a leukodepleted platelet concentrate would be expected to reduce the glycolysis in the platelets and to maintain platelet quality as taught by Sweeney *et al.*

Although the applicant has recognized another advantage which would flow naturally from following the suggestions of the prior art, this fact cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Although the intent of applicant's method is different from the intent of the disclosed method, the one step of adding carnitine or an ester of carnitine in the same concentration is the same. Thus, the results of the method, suppression of bacterial growth, would reasonably be assumed to be the same as the result claimed.

It is not relevant to the analysis of the claimed method that the reference makes no mention of suppressing bacterial growth. Discovery of a new benefit

for an old process does not render the old process patentable. *In re* Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *In re* Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 3/24/08 have been fully considered but they are not persuasive.

Applicant argues that Sweeney *et al.* or US '536 do not disclose that the method disclosed by Sweeney *et al.* would work with leukoreduced platelets. It is correct that the reference of Sweeney *et al.* is not anticipatory. Therefore, indeed, it lacks the disclosure of use of leukoreduced platelets. However, it has been fully explained above that platelets are known have glycolytic enzymes, the functioning of which impairs the quality of the platelets during storage (Sweeney *et al.*) which impairs, and that glycolysis can be lessened by the addition of carnitine. In the absence of evidence to the contrary, which applicant has not supplied, it is reasonable to assume that platelets are platelets, i. e. even if a more purified composition of platelets is used, the

result, reduced glycolysis upon the addition of carnitine, would be the same. With regard to the arguments concerning US '536 disclosing acyl carnitines used for a different purpose, this argument is not persuasive because the reference is merely employed as stated above, to show that various esters of carnitine are known. It is assumed that any ester of carnitine would perform in the same manner as the acetyl ester because these are all homologous compounds, in the absence of evidence to the contrary. Ogawa *et al.* was simply cited as stated above, to show that leukodepletion is a desirable maneuver in the art of platelet infusion. The arguments are not persuasive because the examiner considers the above rejection to disclose all of the elements of the invention AS CLAIMED and the elements are logically and reasonably linked together, which provides motivation for the combination of references. Applicant argues that he has achieved 8 days of storage of platelets, which applicant alleges is unexpected. However, the applicant does not limit the claims to the unexpected results and does not point to the exemplification which supports the allegation. Thus, the arguments are unpersuasive of error in the rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further

correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is Monday through Friday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Sandra Saucier/

Primary Examiner
Art Unit 1651